

REMARKS**Status of Claims**

Upon entry of the amendment, claims 1-13, 50, 52-55 and 115-122 are pending in this application. Claims 14-49, 51 and 56-114 are cancelled.

Claims 1, 3, 5, 7-12, 50, 52, 53 and 55 are amended herein. New claims 115-122 are added. Applicants respectfully submit that no new matter is introduced.

Claims 1-13 and 50-55 are rejected. Claims 2 and 4 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claims 1-13 and 50-55 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent Application Publication 2002/0072550 to Brady et al. ("Brady"). Claims 1-2, 4-13, 50-55 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by PCT Application Publication WO01/74582 to Thomson ("Thomson"). Claims 1-2, 4-13, 50 and 54-55 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 6,306,424 to Vyakarnam et al. ("Vyakarnam"). Claims 1-4, 9-13 and 50-55 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by PCT Application Publication WO99/24084 to Brady et al. ("Brady '084"). Claim 3 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Thomson as applied to claims 1, 2, 4-13 and 50-55 and further in view of Brady.

In view of the above amendments and following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Support for Amendments

Independent claim 1, as amended, specifies a reticulated elastomeric matrix formed by a reticulation process comprising combustion or chemical reticulation. This language finds support in the application as originally filed, for example, on page 49, lines 1-32. Claim 1 is also amended to specify that the elastomeric matrix comprises a material selected from the group consisting of: (i) polyurethane, (ii) poly(urea-urethane), (iii) polycarbonate polyurethane, (iv) polycarbonate poly(urea-urethane), (v) any polymer formed by the reaction of an isocyanate with a polyol selected from the group consisting of a polycarbonate polyol, a polysiloxane polyol, a hydrocarbon polyol, or any combination thereof; and (vi) any combination thereof. Support for this amendment can be found in the application as originally filed, for example, on page 34, line 1 to page 38, line 25 and originally filed claims 12. Claim 1, as amended, includes the claim element that the elastomeric matrix has an isocyanate index of about 0.9 to about 1.029. Support for this amendment is found in the application as originally filed, for example, on page 39, lines 10-12. Independent claim 1, as amended, specifies that the elastomeric matrix is substantially free of allophanate, biuret and isocyanurate linkages. This language finds support in the application as originally filed, for example, on page 20, lines 28-29.

Support for the amendment to claim 9 can be found in the application as originally filed, for example, on page 26, lines 26-30.

The amendment to claim 11 finds support in the application as originally filed, for example, on page 25, lines 11-14.

Support for the amendment to claim 12 can be found in the application as originally filed, for example, on page 26, lines 6-8.

Support for new claim 115 can be found in the application as originally filed, for example, on page 79, lines 2-11.

New claims 116 finds support in the application as originally filed, for example, on page 28, lines 5-6.

New claim 117 finds support in the application as originally filed, for example, page 40, lines 22-24.

New claims 120 and 121 find support in the application as originally filed, for example, page 39, lines 32-33.

New claim 122 finds support in the application as originally filed, for example, page 35, lines 8-13.

Election/Restrictions

The Office Action maintains and makes final the restriction requirement of February 27, 2008. The Examiner maintains the requirement for restriction and indicated that “[a] complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action.” Office Action, page 2. In the interest of expediting the prosecution of this application, and without conceding to the Examiner’s restriction, Applicants have cancelled claims 14-49 and 56-114.

Response to Rejection Under 35 U.S.C. §112

Claims 2 and 4 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office Action contends that the recitation of

“biodurable” is unclear because “[i]t can not be determined what degree of bio-resiliency is intended to be encompassed by the claimed term ‘biodurable’.” Applicants respectfully traverse this ground of rejection.

The specification as originally filed provides that

... the term “biodurable” describes elastomers and products that are stable for extended periods of time in a biological environment. Such products should not exhibit significant symptoms of breakdown or degradation, erosion or significant deterioration of mechanical properties relevant to their employment when exposed to biological environments for periods of time commensurate with the use of the implantable device.

Specification, page 13, lines 17-22. Moreover, contrary to the Office Action’s contention, claims 2 and 4 provide specific standards for ascertaining the requisite degree of biodurability. Specifically, claim 2 recites “biodurable for at least 29 days” and claim 4 recites “biodurable for at least 6 months.” The minimum time length for biodurability recited by Applicants’ claims 2 and 4 sets forth the requisite degree resiliency such that one of ordinary skill in the art would be reasonably apprise of the scope of Applicants’ invention. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

Response to Rejection Under 35 U.S.C. §102(b) Based on Brady

Claims 1-13 and 50-55 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent Application Publication 2002/0072550 to Brady et al. (“Brady”). Applicants respectfully traverse this ground of rejection.

A rejection of claims as anticipated under 35 U.S.C. §102(b) requires a showing that each and every claim limitation be identically disclosed in the applied reference. If even one claim limitation is not disclosed in the reference, the claim is patentable over the reference.

Independent claim 1, as amended, specifies that the “elastomeric matrix has an isocyanate index from about 0.9 to about 1.029 and is substantially free of allophanate, biuret and isocyanurate linkages.” In contrast, Brady describes a porous biomaterial characterized “in that it has a void content in excess of 85%, is cross-linked, the hard phase contains isocyanurate linkages and materials are biostable.” Brady, ¶[0006](*emphasis added*). Brady does not teach or suggest the matrix recited by Applicants’ claims. Rather, Brady describes a biomaterial formed using a trimerisation agent to promote the formation of isocyanurate linkages and an excess of isocyanate in the reaction chamber. *See* Brady, ¶¶ [0035], [0057] and [0082]. Brady also describes a material having an isocyanate index between 1.03 and 1.20, which is above the isocyanate index recited by Applicants claims. *See* Brady, ¶[0035].

Moreover, independent claim 1, as amended, recites that the reticulated elastomeric matrix is “formed by a reticulation process comprising combustion or chemical reticulation.” The term “reticulation” as defined by Applicants’ specification “generally refers to a process for removing such cell walls not merely rupturing them by a process of crushing.” Specification, page 46, lines 8-10. Brady makes no mention of either combustion or chemical reticulation. In contrast, Brady states that “[r]eticulation of the scaffold can be carried out by crushing.” As stated in Applicant’s specification, crushing is undesirable and “creates debris that must be removed by further processing.” Specification, page 46, lines 9-10.

For at least these reasons, Applicants respectfully request withdrawal of this ground of rejection.

Response to Rejection Under 35 U.S.C. §102(b) Based on Thomson

Claims 1-2, 4-13, 50-55 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by PCT Application Publication WO01/74582 to Thomson ("Thomson"). Applicants respectfully traverse this ground of rejection.

Independent claim 1, as amended, recites that the reticulated elastomeric matrix is "formed by a reticulation process comprising combustion or chemical reticulation." Thomson does not teach or suggest a reticulated elastomeric matrix formed by combustion or chemical reticulation. Thomson makes no mention of chemical reticulation of any type. As described in Applicants' specification, "combustion reticulation may be employed in which a combustible atmosphere, e.g., a mixture of hydrogen and oxygen, is ignited, e.g., by a spark." Specification, page 49, lines 18-20. Thomson generically describes "[u]sing heat and pressure in specially designed vessels, a flexible skeletal foam structure without cell membranes is produced," but makes no mention of igniting or generating a spark, which is an essential aspect of combustion reticulation. *See* Thomson, page 10, lines 21-23. Therefore, Thomson also does not teach or suggest a reticulated elastomeric matrix formed by combustion reticulation.

In addition, independent claim 1, as amend, specifies an elastomeric matrix having "an isocyanate index of about 0.9 to about 1.029 and is substantially free of allophanate, biuret and isocyanurate linkages." Thomson makes no mention of an isocyanate index, much less a specific isocyanate index of about 0.9 to about 1.029. Additionally, in discussing its prepolymers, Thomson states that crosslinking sites are developed, when necessary, during the prepolymer formation by certain techniques, including:

1. The addition of water to the prepolymer polyols to form urea and subsequently biuret linkages in the prepolymer;

2. The formation of allophanate linkages by prolonged heating at elevated temperatures;

Thomson, page 14, lines 15-19.

For at least these reasons, Applicants respectfully request withdrawal of this ground of rejection.

Response to Rejection Under 35 U.S.C. §102(b) Based on Vyakarnam

Claims 1-2, 4-13, 50 and 54-55 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 6,306,424 to Vyakarnam et al. ("Vyakarnam"). Applicants respectfully traverse this ground of rejection.

Independent claim 1, as amended, recites "an elastomeric matrix comprising a material selected from the group consisting of: (i) polyurethane, (ii) poly(urea-urethane), (iii) polycarbonate polyurethane, (iv) polycarbonate poly(urea-urethane), (v) any polymer formed by the reaction of an isocyanate with a polyol selected from the group consisting of a polycarbonate polyol, a polysiloxane polyol, a hydrocarbon polyol, or any combination thereof; and (vi) any combination thereof." Vyakarnam does not teach or suggest a reticulated elastomeric matrix comprising any of the materials listed in (i) through (v) of Applicants' claim 1. Instead, Vyakarnam provides a long list of absorbable polymers, such as ϵ -caprolactone-co-glycolide and ϵ -caprolactone-co-lactide. See Vyakarnam, col. 9 line 51 to col. 11, line 25, and col. 12, lines 16-18. However, none of the absorbable polymers listed therein describe a polyurethane, poly(urea-urethane), polycarbonate polyurethane, polycarbonate poly(urea-urethane), or any polymer formed by the reaction of an isocyanate with a polyol, as recited by Applicants' claim 1.

The Office Action contends that "Vyakarnam et al. discloses preparations of reticulated/porous, biostable elastomeric materials...." Office Action, 4. It appears that the

Office Action has erroneously equated the term “porous” with the term “reticulated” recited by Applicants’ claims. As would be understood by one of ordinary skill in the art, a reticulated matrix is different and distinct from a porous material. For example, as discussed in Applicants’ specification a reticulated matrix includes “a continuous interconnected void phase 14, the latter being a principle feature of a reticulated structure.” Specification page 15, lines 15-16. Moreover, the reticulated matrix may comprise a continuous network of solid structures, such as struts 16 and intersections 18, without any significant terminations, isolated zones or discontinuities, other than at the boundaries of the elastomeric matrix, in which network a hypothetical line may be traced entirely through the material of solid phase 12 from one point in the network to any other point in the network.” Specification page 17, lines 16-21. The reticulated matrix may provide “fluid permeability through the implantable device and permits cellular ingrowth and proliferation into the interior of the implantable device.” Specification, page 5, line 20-22.

Independent claim 1, as amended, recites that the reticulated elastomeric matrix is “formed by a reticulation process comprising combustion or chemical reticulation.” Vyakarnam does not teach or suggest a reticulated elastomeric matrix formed by either combustion reticulation or chemical reticulation. Instead, Vyakarnam describes a freezing step phase that “separates the polymer solution and vacuum drying step removes the solvent by sublimation and/or drying leaving a porous polymer structure or an interconnected open cell porous foam.” Vyakarnam, col. 12, lines 62-65. The foam of Vyakarnam is formed by a completely different reticulation process as that recited by Applicants’ claim 1.

For at least these reasons, Applicants respectfully request withdrawal of this ground of rejection.

Response to Rejection Under 35 U.S.C. §102(b) Based on Brady '084

Claims 1-4, 9-13 and 50-55 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by PCT Application Publication WO99/24084 to Brady et al. ("Brady '084"). Applicants respectfully traverse this ground of rejection.

The Office Action contends that Brady '084 "discloses preparation of porous, biostable, polycarbonate based polyurethane elastomeric materials reading on the preparations of applicants' claims...." Office Action, 6. (*emphasis added*.) Applicants respectfully disagree. Applicants' claim 1 specifies an implantable device comprising a reticulated elastomeric matrix. As discussed above, one skilled in the art would understand that the term "reticulated" defines a different structure than the term "porous" and the two terms are not interchangeable. Applicants' specification further clarifies that a reticulated matrix is distinct from a porous product. In particular, a reticulated matrix may be obtained after further processing of a porous foam. Applicants disclose that a reticulate matrix may be formed by further processing of a porous product to "remove at least a portion of any existing interior "windows", i.e. the residual cell walls 22...." Specification, page 45, lines 25-28. As described by the specification, "[r]eticulation tends to increase porosity and fluid permeability." Specification, page 45, lines 28-29.

The Office Action has not shown and Brady '084 does not teach or suggest a reticulated matrix. The Examiner cites to pages 4 and 5 of Brady '084 as a basis of this rejection; however, nowhere on the cited two pages, or anywhere else in the cited reference does Brady '084 mention a reticulated matrix. At best, Brady '084 provides a generic description for "porous and non-porous" polymers. See Brady, '084, page 1, line 1. Brady '084 makes no mention of a

continuous interconnected void space, which is a principle feature of a reticulated structure. *See* Specification page 15, lines 15-16.

In addition, independent claim 1, as amended, specifies that the elastomeric matrix “is substantially free of allophanate, biuret and isocyanurate linkages.” In contrast, Brady’084 describes that “[t]he isocyanates react under suitable conditions with the active hydrogens of the urethane and urea linkages to form biuret and allophanate linkages.” Accordingly, Brady ’084 does not teach or suggest a reticulated elastomeric matrix as recited by Applicants’ claims.

For at least these reason, Applicants respectfully request withdrawal of this ground of rejection.

Response to Rejection Under 35 U.S.C. §103(a)

Claim 3 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Thomson as applied to claims 1, 2, 4-13 and 50-55 and further in view of Brady. Applicants respectfully traverse this ground of rejection.

To establish a *prima facie* case of obviousness, it is elementary that the combination of cited references must teach or suggest all the claim limitations. *See In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1999). As no such *prima facie* case can be established for the currently pending claims, Applicants respectfully traverse this ground of rejection, as set forth more fully below.

As discussed above, neither Thomson nor Brady teach or suggest, alone or in combination, a reticulated elastomeric matrix having “an isocyanate index of about 0.9 to about 1.029 and is substantially free of allophanate, biuret and isocyanurate linkages.” Moreover, independent claim 1, as amended, recites that the reticulated elastomeric matrix is “formed by a reticulation process comprising combustion or chemical reticulation.” As discussed above,

Thomson does not teach or suggest a reticulated elastomeric matrix formed by combustion or chemical reticulation.

Inasmuch as the cited combination of references fail to teach or suggest Applicants' claimed invention, and notably fail to teach a reticulated elastomeric matrix having an isocyanate index of about 0.9 to about 1.029 and is substantially free of allophanate, biuret and isocyanurate linkages, there simply is no basis for the Office Action's contention that "it would have been obvious for one having ordinary skill in the art to have employed the polycarbonate polyurethane forming materials disclosed by Brady et al. as the polyurethane forming materials used in WO'582 for the purpose of producing acceptable stable, implant materials." Office Action, 7. Brady states that reticulation "has the disadvantage that reticulated pores will tend to be more irregular in shape." See Brady, ¶[0112]. It is respectfully submitted that the Office Action's contention is impermissibly based on hindsight because one of ordinary skill in the art would not have combined the materials described in Brady with a reticulated structure, which Brady characterizes as disadvantageous.

Accordingly, Applicants submit that Thomson and Brady, whether taken alone or in combination, do not suggest the methods of the present claims. Reconsideration and withdrawal of these rejections is respectfully requested.

Having distinguished the independent claims from the art of record, Applicants submit that the claims dependent therefrom are patentable for at least the same reasons. However, Applicants reserve the right to separately address the patentability of the dependent claims in the future, should that be necessary.

Provisional Double Patenting

Claims 1-13 and 50-55 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being allegedly unpatentable over claims 1-101 of copending Application No. 11/652,763. Claims 1-13 and 50-55 are also provisionally rejected on the ground of non-statutory obviousness-type double patenting as being allegedly unpatentable over claims 1-6, 8-22, 41-46 and 89-141 of copending Application No. 10/848,624. Because these are provisional rejections, Applicants kindly request that this rejection be held in abeyance pending the determination of patentable subject matter.

CONCLUSION

Based on the foregoing remarks, Applicants submit that they have completely responded to the restriction requirement. Applicants respectfully request reconsideration and withdrawal of the restriction requirement and examination of all the claims in this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-3732**, Order No. **14596-105011**. In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-3732**, Order No. **14596-105011**.

Respectfully submitted,
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